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INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/029148

International filing date (day/month/year)
08.09.2004

Priority date (day/month/year)
23.10.2003

International Patent Classification (IPC) or both national classification and IPC
G01B9/02, A61B5/00

Applicant
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 19,71-79 (all in part)

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 19,71-79 (all in part)
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	7-14, 16, 19 (in part), 34-43, 46-70, 71-79 (in part), 81-93
	No: Claims	1-6, 15, 18, 20-33, 44, 45, 80
Inventive step (IS)	Yes: Claims	none
	No: Claims	1-18, 19(in part), 20-70, 71-79(in part), 80-93
Industrial applicability (IA)	Yes: Claims	1-93
	No: Claims	

2. Citations and explanations

see separate sheet

Cited documents

- D1: WO 98/35203 A (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 13 August 1998 (1998-08-13)
D2: WO 97/32182 A (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 4 September 1997 (1997-09-04)
D3: WO 92/19930 A (MASSACHUSETTS INSTITUTE OF TECHNOLOGY; SWANSON, ERIC, A) 12 November 1992 (1992-11-12)
D4: WO 00/58766 A (SCIMED LIFE SYSTEMS, INC) 5 October 2000 (2000-10-05)
D5: US-B1-6 501 551 (TEARNEY GUILLERMO ET AL) 31 December 2002 (2002-12-31)
D6: US-A-4 601 036 (FAXVOG ET AL) 15 July 1986 (1986-07-15)
D7: US-A-4 868 834 (FOX ET AL) 19 September 1989 (1989-09-19)
D8: EP-A-0 251 062 (FUJITSU LIMITED) 7 January 1988 (1988-01-07)
D9: US 2003/023153 A1 (IZATT JOSEPH A ET AL) 30 January 2003 (2003-01-30)
D10: US-B1-6 341 036 (TEARNEY GUILLERMO J ET AL) 22 January 2002 (2002-01-22)

Section III

Claims 19 and 71-79 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

For the purposes of the search and examination these claims have been interpreted as comprising the features of the embodiment with the grating and rotating polygon as shown eg in figure 6, which according to the description seems to be the features which can enable the desired result.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/029148

Section V

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

D1 discloses an apparatus comprising (see figure 1 and page 3, line 10 to page 4, line 2):

- a first arrangement (tunable laser 14) providing one first radiation to a sample (the optical path leading to sample 38) and a second radiation to a reference (optical path leading to reference mirror 34); wherein a frequency of radiation provided by the first arrangement varies over time (frequency tuned laser 14);
- at least one second arrangement detecting an interference between a third and a fourth radiation associated with the first and second electromagnetic radiations (interferometer 18);

With respect to the feature of the non-reflective reference it is noted that in D1, page 16, last line to page 17 first 6 lines it is clearly stated that the reference reflection can be made as small as possible.

Thus, D1 discloses an apparatus having all the features of independent claim 1.

The same objection is raised against corresponding method claim 20.

2. With respect to the further independent claims the following objections occur:

Claims 21 and 45: these claims differ from claim 1 in that (i) the reference is not defined as non-reflective and (ii) the feature that "the spectrum contains multiple frequencies at a particular time". As stated above D1 discloses both reflective and non-reflective references so that feature (i) is not novel over D1. The feature (ii) is not clear in that the wording "at a particular time" is obscure. When looking at the description it would appear that what is meant is the embodiment with a broadband source which is then filtered (eg figure 6). Such broadband sources are generally well known in connection with an OCT instrument, (see eg D2, page 2, line 15). Thus, these claims are not considered inventive.

Claims 46 and 69: these claims differ from claim 1 in that (i) the reference is not defined as non-reflective and (ii) the feature of using two different polarization states. Feature (i) is disclosed in D1 as outlined above. The use of polarization is common practice in OCT systems (see eg D3, figure 11) and thus these claims are not considered inventive.

Claims 71 and 79: as stated above under Section III these claims have been interpreted as comprising the rotating polygon and grating arrangement. However, as can be seen from documents D6 to D8 such arrangements are well known in the art.

Claim 80: differs from claim 1 in that a further arrangement for shifting the frequency is included. However, such arrangements are standard in OCT technique and is also mentioned eg in D1, figure 6, element 320.

Claims 81, 92 and 93: these claims include further to the features of claim 1 the feature of sampling the data in a first format and then transferring this data to a second format. This is mainly done in order to provide linearity. However, such format changing is well known in the art of sampling techniques (see also D3 and D9).

3. The dependent claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, since they all relate to different well known features of OCT systems:

Frequency shifting is generally known as stated above.

The use of a transverse scanning probe is already known from D1, figure 1. Further, as shown in document D4 also rotary probes with fibre-optic catheter is well known.

The use of a bandpass filter is a standard technique, see eg D3.

A dual balanced receiver is eg disclosed in D1, p. 8, line 18.

Polarization measuring techniques are eg known from D3, figure 11 (see also D8,

figure 7).

Phase shifting techniques are known eg from D1.

The tuning rates mentioned are also inherent in the rotating polygon arrangements of the prior art.

A semiconductor gain medium is eg disclosed in D1, p. 4, line 19.

The sampling techniques defined are all standard in the art of sampling of measurement data. Reference is also made to D1, D3 and D9.